Summary of the Meeting of the CON Task Force

May 26, 2005

Maryland Health Care Commission 4160 Patterson Avenue Baltimore, Maryland 21215

Task Force Members Present

Robert E. Nicolay, CPA, Chairman
Larry Ginsburg
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Annice Cody
Hal Cohen
Natalie Holland
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Michelle Mahan
Henry Meilman, M.D.
Anil K. Narang, D.O.

Lawrence Pinkner, M.D.

Frank Pommett, Jr.

Barry F. Rosen, Esquire

Christine M. Stefanides, RN, CHE

Joel Suldan, Esquire

Jack Tranter, Esquire

Terri Twilley, MS, RN

Task Force Members Absent

Commissioner Robert Moffit, Ph.D. Douglas H. Wilson, Ph.D.

Members of the Public Present

Andrew Cohen, AGC and Associates Miles Cole, Maryland Department of Business and Economic Development Jack Eller, Esquire, Ober, Kaler, Grimes, & Shriver Sean Flanagan, St. Joseph Medical Center
Christopher Hall, Adventist Healthcare
Wynee Hawk, Greater Baltimore Medical Center
Donna Jacobs, University of Maryland Medical System
Anne Langley, Johns Hopkins Health System
Vanessa Purnell, MedStar Health
Pegeen Townsend, MHA: Association of Maryland Hospitals & Health Systems

1. Call to Order and Introductions

Chairman Robert E. Nicolay called the meeting to order at 1:05 p.m. He welcomed the members of the Task Force and members of the public in attendance. At Chairman Nicolay's request, the Task Force members introduced themselves. Pamela Barclay, Interim Executive Director, introduced members of the Commission's staff. Chairman Nicolay noted that the Task Force has an ambitious schedule of meetings through the middle of August and that the Commission's staff will work closely with the Task Force. He emphasized that members of the public are welcome at each meeting.

2. Overview of Task Force Objectives, Report Development Process, and Timetable

Chairman Nicolay provided an overview of the objectives and timetable. The purpose of the Task Force is to enhance the credibility and integrity of the Certificate of Need program by conducting a stakeholder driven review, using a combination of the broadly representative Task Force and a public comment process to gain insight and make recommendations to enhance and improve the program. The objectives of the Task Force: review and recommend modifications in the scope of services and facilities regulated under the Certificate of Need program; review and recommend enhancements in the CON review process; and review and recommend enhancements in the monitoring of CON projects under development.

Chairman Nicolay announced that the Task Force will convene a Public Forum to solicit recommendations on the CON program on Tuesday, June 7, 2005 from 10:00 a.m. to 1:00 p.m. at the offices of the Commission. The Public Forum will provide an opportunity for the Task Force to receive comments from stakeholders and members of the public. The Task Force will develop a report summarizing the findings and recommendations for presentation to the full Commission. The Commission will review the Task Force report and release it for public comment in September; followed by an evaluation of public comments received and modifications to the Final Recommendations in October. The Commission will take Final Action on the Task Force recommendations in November and, in December, will develop and approve an implementation plan with recommendations regarding modifications to administrative, regulatory, and statutory provisions.

3. Discussion of the June 7, 2005 Public Forum

Chairman Nicolay noted that the Public Forum has been well publicized. Staff has sent out nearly 700 notices regarding the forum. Speakers will sign in on the morning of the Forum and then the Task Force will determine the length of time allotted to the speakers based on the number of presenters requesting to speak. Following the Public Forum, the Commission will continue to receive written testimony through June 10th. The staff will subsequently summarize all testimony for presentation to the Task Force at its June 23rd meeting.

4. Background: Maryland Certificate of Need Program

Ms. Barclay presented a background briefing on Maryland's Certificate of Need program. Key components of her presentation included a discussion of the scope of the CON program. A CON is required before a new health care facility/service is built, developed, or established by hospitals; nursing homes; ambulatory surgical facilities with two or more operating rooms; residential treatment centers; intermediate care facilities (substance abuse and developmental disabilities); Medicare-certified home health agencies; and hospice agencies. A CON is also required for certain patient-care related capital expenditure projects that involve a health care facility (e.g., construction and/or renovation) above the current threshold of \$1,650,000. Additionally, a CON is required before a new, highly specialized service such as Open Heart Surgery, Organ Transplant Surgery, Neonatal Intensive Care (NICU), or Burn Care is developed by a hospital.

A CON is <u>not</u> required for hospital capital expenditures over the threshold if no rate increase is pledged (for certain eligible projects); conversion of an existing hospital to a limited service hospital; closure of a hospital or medical service provided by a hospital; assisted living facilities; major medical equipment (e.g., CT scanners, linear accelerators, catheterization laboratories); kidney dialysis centers; capital expenditures to acquire health care facilities; or waiver beds for non-hospital facilities.

Ms. Barclay discussed the levels of CON review. Determinations of non-coverage are initiated by a letter to the Commission regarding acquisitions, waiver beds, one operating room, or hospital capital projects eligible for the "pledge" not to increase rates. In these circumstances, the determination is made by the Commission's Executive Director within thirty days of the applicant's request. Exemptions from CON Review are initiated by an applicant's Request for Exemption from CON Review in circumstances such as a merger or consolidation of two or more hospitals or other health care facilities, or the closure of a hospital in jurisdictions with fewer than three hospitals. Decisions are made by the Commission upon the analysis and recommendation of staff within forty-five days of the notice. There are no interested parties permitted in applications for determination on non-coverage or exemption from CON Review. A CON Review is initiated by an applicant's writing a Letter of Intent, followed by a CON application within sixty days, for a new health care facility or capital expenditures above the threshold. The Commission makes decisions on applications for CON following a staff recommendation in instances that are uncontested, or following a Commissioner-

Reviewer's recommendation when there are interested parties in either a contested or comparative review. The time frames for decisions made in these circumstances are from ninety days to 150 days when an Evidentiary Hearing is held.

Ms. Barclay discussed a statistical breakdown of the types of CON decisions by level of review from 2000 through 2004 and an estimation for 2005. During that time, Commission decisions for CON approvals, denials, and modifications have ranted from a low of 8 decisions in 2001 to a estimate of 37 decisions in 2005. Further, the costs of acute general and special hospital projects approved or reviewed by the CON program has increased from \$500 million during 1991-93 to approaching \$3 billion for 2003-2005.

Key trends in health care facility projects include increased numbers of treatment beds and observation/admission units in emergency departments; larger and increased numbers of operating rooms; increased numbers of intensive care unit and medical/surgical beds, conversion to private rooms and replacement of hospital facilities; addition of new rehabilitation and obstetrics services; closure of subacute, psychiatric, and obstetrics services; and the addition of patient safety protocols such as new information systems technology (e.g., computerized physician order entry) for acute care hospitals. Key trends in nursing homes include replacement facilities, conversion to private rooms, and the redevelopment of off-line capacity as bed needs increase. Ambulatory surgery facilities' capacity is increasing through the addition of operating rooms and hospital-affiliated free standing ambulatory surgical facilities. Trends in specialized health care services include applications for new services in primary and elective angioplasty and neonatal intensive care units.

The Certificate of Need Review Criteria set forth in COMAR 10.24.01.08G(3)(a)-(f) require the Commission to consider State Health Plan standards, policies, and projections; demonstrated or projected need for the new facility or service; the availability of more cost-effective alternatives; the viability of the project with respect to the availability of financial and non-financial resources (community support and available staff, and other resources necessary to sustain the project); compliance with the conditions of previous CONS; and the impact on existing providers. The State Health Plan ensures that rational, planned growth in capacity is based on community need and benefit and that projects are reviewed based on an objective measure of quality, geographic and financial access, and affordability. Further, the development of the State Health Plan assures and public process and the coordination of policy among the Commission, Office of Health Care Quality, Medicaid, the Health Services Cost Review Commission and the Department of Aging.

Ms. Barclay presented a summary of the evolution of the CON program including changes in process and coverage. In 1985, Health Care Cost Containment legislation deregulated major medical equipment and established the exemption from CON for certain projects in statute. In 1986, changes in CON regulation were made for ambulatory surgical facilities. In 1988, changes in CON regulation for hospital capital expenditures included the deregulation of hospital capital expenditures provided that there was no rate increase ("the Pledge"); the capital review threshold was raised from

\$600,000 to \$1,250,000; and CON was explicitly required to establish open heart surgical programs, organ transplant surgery, burn, or NICU services. The HealthCare Reform Act of 1995 created further changes in the CON regulation of ambulatory surgical facilities and changes in the CON process. The Hospital Cost Containment and Capacity Act in 1999 included changes in hospital closure rules, the elimination of waiver beds for acute care hospitals, the annual calculation of licensed acute care hospital beds as 140% of the average daily census; and the spousal carve-out provision permitting direct admission to a continuing care retirement community. Further changes in the CON regulation of CCRCs were adopted in 2000 with the CON-excluded beds at CCRC nursing homes raised from 20 to 24% for some CCRCs and limited direct admissions to CCRC nursing homes permitted.

Ms. Barclay discussed a comparative profile of Maryland and of CON programs in the United States as of February 2004 and capital expenditure review thresholds for state CON programs in 2004. She pointed out distinctive aspects of Maryland's CON program. Maryland's planning based approach to regulation includes one of the most extensive data collection and analysis support structures in the nation with extensive consultation with health services providers through advisory committees such as the recently convened Technical Advisory Committee on Outcome Assessment in Cardiovascular Care and its three subcommittees. Maryland's use of waivers and pilot projects to study implications in a dynamic, rapidly changing environment is also unique. As many as 22 other states regulate major medical equipment while Maryland excludes it from regulation but does include home health and hospice services. Maryland's unique approach to outpatient surgery and its linkage to and work with the Health Services Cost Review Commission also sets it apart from other states.

Chairman Nicolay thanked Ms. Barclay for her presentation and asked if Task Force members had any questions. Joel Suldan asked for further information regarding the actual time taken for CON reviews. Ms. Barclay said that staff will provide that information. Barry Rosen asked whether there has been consideration of triggering a CON review based upon the percent of revenue of the CON applicant, rather than the capital expenditure threshold. Ms. Barclay said that staff will research that issue. Albert L. Blumberg, M.D., F.A.C.R. asked if Maryland's CON program was created in the early 1970's. Susan Panek, Chief of CON, replied that it was created in 1968.

5. Future Meeting Schedule

June 7, 2005: Public Forum, 10:00 a.m.

June 23, 2005: Task Force Meeting, 1:00 p.m.

July 14, 2005: Task Force Meeting, 1:00 p.m.

July 28, 2005: Task Force Meeting, 1:00 p.m.

August 11, 2005: Task Force Meeting, 1:00 p.m.

6. Other Business

William Chester, M.D. asked if surrogates could attend meetings in the absence of task force members. Chairman Nicolay responded that surrogates would be acceptable as long as the Commission was notified in advance. Dr. Chester asked if email correspondence was permissible and Chairman Nicolay replied that email correspondence would not be a problem. Frank Pommett, Jr. asked if staff will be making comments to the Task Force. The Chairman replied the Commission does not want the review to be staff-driven, but that staff comment would be solicited and considered. Joel Suldan suggested that staff make recommendations regarding what services need to be regulated. He wanted further information regarding why some services are regulated and others are not. The Chairman said that these questions will be considered. Adam Kane requested that task force members be given a copy of the State Health Plan. Chairman Nicolay said that copies of the State Health Plan will be provided to all members of the task force. Terri Twilley asked whether the task force will be looking at CON activity in other states, for example, in Vermont with regard to home health care and fair trade issues. Chairman Nicolay said that the task force would be looking at input from everyone.

7. Adjournment

Chairman Nicolay said that he is looking forward to working with everyone and thanked them for coming. The meeting was adjourned at 2:07 p.m.